

### **REMARKS**

Claims 1 – 9 were pending. All claims were objected to based on the use of unacceptable transitional phrases. All claims were also rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,756,067 to Redgrave. Applicant requests reconsideration of the rejection and the objection.

#### **The Objection**

Claims 1 – 9 have been canceled and substantially rewritten as new claims 10 – 21. The rewritten claims include new transitional phrases. Therefore, Applicant requests that the objection be withdrawn.

#### **35 U.S.C. 102(b)**

Claim 10 is the only new independent claim. The claim is somewhat similar in scope to original claim 1. However, it now makes clear that the disclosed marker may now be metabolized by a human body (see original claim 3) and may also be identified in its unmetabolized state in a bodily excretion. The claim also includes additional elements related to the collection and testing of a sample. New dependent claims 11 - 22 are similar to original claims 2 – 9. New dependent claims 23 and 24 further clarify the term “bodily excretion” from claim 10, and provided a time range between the administration step and the collecting step. All of the dependent claims should be allowed since they depend from an allowable independent claim.

#### **About the Diagnostic Test**

The disclosed diagnostic test may be directed to solving a problem that is encountered in drug testing. As described on page 4 of the specification, drug test subjects may occasionally

spit into a test container in order to adulterate or otherwise throw off the test results. Since drug tests are often taken in private, the problem manifests itself in the fact that a test screener cannot be certain why or how a test was adulterated or if the results are accurate.

To address the problem, the disclosed diagnostic test may use a marker that may be metabolized by the body, but that may also be detected if found in its unmetabolized form. Thus, if the marker is mixed into a test drink, it should not appear in a subsequent urine test. Conversely, if the marker does appear in a test, a screener may presume that the test subject inappropriately introduced the unmetabolized marker into the test container.

#### **Redgrave**

Redgrave does not teach the claimed diagnostic method. Instead, it expressly relied upon the use of a “composition being capable of metabolism by normal physiological pathways such that at least one labelled metabolite is detectable in the blood or bodily waste of a patient being tested”. See Col 3, lines 15 – 18 (*emphasis added*). Redgrave, therefore, does not anticipate claim 10 since it is directed to a test for a tagged metabolite, and not for an unmetabolized marker. Moreover, to the extent that both Redgrave and the claimed method use substances that may be metabolized, their respective uses of those substances is entirely at odds. Redgrave tests for a tagged metabolite, while in the claimed test it is advantageous for a metabolized marker to not be detected. Accordingly, Applicant requests that the rejection under Section 102(b) be withdrawn.

Applicant also respectfully disagrees that Redgrave teaches all of the markers set forth in the dependent claims. Applicant, for example, can find no reference in Redgrave to a xanthine

derivative. Accordingly, Applicant requests that the Examiner specifically identify where each of the claimed markers may be found in the Redgrave reference.

In view of the above amendment, Applicant submits that the pending application is now in condition for allowance.

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Respectfully submitted,

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